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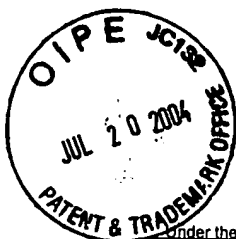
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PTO/SB/21 (08-03)

Approved for use through 08/30/2003. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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TRANSMITTAL FORM (to be used for all correspondence after initial filing)	Application Number	09/827,255
	Filing Date	4/5/2001
	First Named Inventor	Wong
	Art Unit	1635
	Examiner Name	James Schultz
Total Number of Pages in This Submission	Attorney Docket Number	32144183.1336

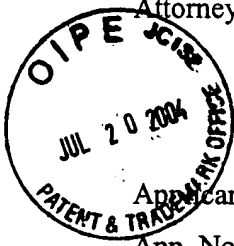
ENCLOSURES (Check all that apply)		
<input type="checkbox"/> Fee Transmittal Form	<input type="checkbox"/> Drawing(s)	<input type="checkbox"/> After Allowance communication to Technology Center (TC)
<input checked="" type="checkbox"/> Fee Attached \$1605	<input type="checkbox"/> Licensing-related Papers	<input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences
<input checked="" type="checkbox"/> Amendment/Reply	<input checked="" type="checkbox"/> Petition to Revive	<input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief)
<input type="checkbox"/> After Final	<input type="checkbox"/> Petition to Convert to a Provisional Application	<input type="checkbox"/> Proprietary Information
<input checked="" type="checkbox"/> Affidavits/declaration(s)	<input type="checkbox"/> Power of Attorney, Revocation	<input type="checkbox"/> Status Letter
<input type="checkbox"/> Extension of Time Request	<input type="checkbox"/> Change of Correspondence Address	<input checked="" type="checkbox"/> Other Enclosure(s) (please identify below):
<input type="checkbox"/> Express Abandonment Request	<input type="checkbox"/> Terminal Disclaimer	Postcard acknowledgement
<input type="checkbox"/> Information Disclosure Statement	<input type="checkbox"/> Request for Refund	
<input type="checkbox"/> Certified Copy of Priority Document(s)	<input type="checkbox"/> CD, Number of CD(s) _____	
<input type="checkbox"/> Response to Missing Parts/Incomplete Application	Remarks	
<input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53		

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT	
Firm or Individual name	Pamela J. Wong, Reg. No. 54,765
Signature	
Date	7/21/04

CERTIFICATE OF EXPRESS MAILING	
I hereby certify that the papers enclosed herein are being deposited with the United States Postal Service "Express Mail post Office to Addressee" service under 37 C.F.R. 1.10 on the date indicated above and addressed to Attn: Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450.	
Typed or printed name	Pamela J. Wong, Reg. No. 54,765
Signature	
Date	7/21/04

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Wong ET AL

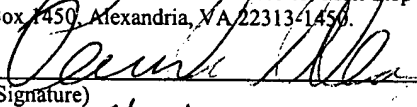
App. No.: 09/827,255

Title: COMPOSITIONS AND METHODS FOR THE TARGETED DELIVERY OF AGENTS TO TREAT LIVER CANCER

Filing Date: April 5, 2001

Art Unit: 1635

Examiner: James Schultz

"CERTIFICATE OF EXPRESS MAIL" No. EV183594695US
DATE OF DEPOSIT: 7/21/2004
I, Pamela J. Wong, hereby certify that this paper or fee is being deposited with the United States Postal Service with sufficient postage "VIA EXPRESS MAIL POST OFFICE TO ADDRESSEE" service under 37 C.F.R. 1.10 on, or before the date indicated above and is addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

(Signature) 7/21/2004
(Date of Signature)

Mail Stop Petition
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

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**PETITION UNDER 37 C.F.R 1.137(B) TO REVIVE UNINTENTIONALLY
ABANDONED PATENT APPLICATION**

Applicants hereby petition the Commissioner to revive the above mentioned patent application that was unintentionally abandoned. In accordance with 37 C.F.R. § 1.137(b), a Declaration of Pamela J. Wong ("Wong") and a Declaration of Tracey A. Cornish ("Cornish") are included with this filing to establish the pertinent facts of this case.

PETITION UNDER 37 C.F.R 1.137(B) TO REVIVE
UNINTENTIONALLY ABANDONED PATENT APPLICATION
DALDMS/498131.1

PAGE 1 OF 4

I. ARGUMENT

The Manual of Patent Examining Procedure states that when a patent application is unintentionally abandoned for failure to file a timely response, it can be revived. M.P.E.P. § 711.03(c). Specifically, the M.P.E.P. states that a petition to revive must include:

- a) the required reply, unless previously filed;
- b) the petition fee as set forth in 37 C.F.R. § 1.17(m);
- c) a statement that the entire delay in filing the required reply from the due date for the reply until the filing of a grantable petition pursuant to 37 C.F.R. 1.137(b) was unintentional; and
- d) any terminal disclaimer required pursuant to 37 C.F.R. 1.137(d).

Id. For the reasons stated below, each of these requirements is met by this petition.

1. A non-final office action was issued by the Patent Office on December 2, 2003.
2. Response to Office Action was prepared for filing along with a one-month Request for Extension of Time on March 31, 2004. *See Exhibit 1*, Response to an Office Action.
3. A secretary of Baker & McKenzie, Tracey A. Cornish, was instructed to file the Response to Office Action via facsimile transmission under 37 CFR 1.8 by the attorney-of-record. *See Wong*, ¶4.
4. Ms. Cornish unintentionally failed to transmit the response via facsimile. *See Cornish* ¶5.

5. The Patent Examiner contacted the attorney-of-record to inquire about the status of the application and was informed of the unintentional error and the intention to file this petition to revive upon receipt of the Notice of Abandonment. *See* Wong ¶8.

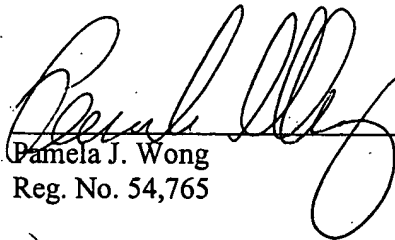
6. A Notice of Abandonment was issued on July 1, 2004. *See* Wong 9.¶

II. CONCLUSION

Based upon these facts, it is clear that the entire delay in filing the required reply from the original due date was the result of unintentional error. Furthermore, because this petition is being filed shortly after the receipt of the Notice of Abandonment, Applicants' attorneys have acted promptly upon discovery of the error. To complete the requirements for this petition, the Response to Office Action and a check in the amount of \$665.00 for this petition are enclosed with this filing. In the event that this check is not sufficient to cover the cost of this petition, the Commissioner is authorized to charge any deficiencies to Deposit Account No. 13-0480, Attorney Docket No. 32144183.1336.

If there are any questions regarding this Petition under 37 C.F.R 1.137(b) to Revive Unintentionally Abandoned Patent Application, please contact the Applicants' attorney at the below-listed telephone number.

Respectfully submitted,



Pamela J. Wong
Reg. No. 54,765

Date: 7/21/2004
BAKER & MCKENZIE
2001 Ross Avenue, Suite 2300
Dallas, Texas 75201
(619) 235-7792 (direct)
(214) 978-3099 (facsimile)

EXHIBIT 1

PTO/SB/97 (08-03)

Approved for use through 07/31/2008. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

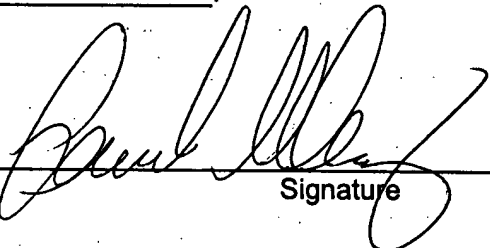
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Certificate of Transmission under 37 CFR 1.8

(703) 872-9306; Examiner Bohultz, Art Group 1835

I hereby certify that this correspondence is being facsimile transmitted to the United States Patent and Trademark Office

on 3/31/04
Date


Signature

Pamela J. Wong, Reg. No. 54,765

Typed or printed name of person signing Certificate

Note: Each paper must have its own certificate of transmission, or this certificate must identify each submitted paper.

FOR S/N 09/827,255

1. Response to Office Action;
2. Petition for Extension of Time - One Month and
3. Facsimile transmission cover sheet

This collection of information is required by 37 CFR 1.8. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1.8 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Under the paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PETITION FOR EXTENSION OF TIME UNDER 37 CFR 1.136(a)		Docket Number (Optional) 32144183.1336
In re Application of Wong et al.		
Application Number 09/827,255	Filed 4/5/2001	
For Compositions and Methods for the Targeted Delivery ...		
Art Unit 1835	Examiner Bohultz	

This is a request under the provisions of 37 CFR 1.136(a) to extend the period for filing a reply in the above identified application.

The requested extension and appropriate non-small-entity fee are as follows (check time period desired):

- ☒ One month (37 CFR 1.17(a)(1)) \$ 110.00
- ☐ Two months (37 CFR 1.17(a)(2)) \$ _____
- ☐ Three months (37 CFR 1.17(a)(3)) \$ _____
- ☐ Four months (37 CFR 1.17(a)(4)) \$ _____
- ☐ Five months (37 CFR 1.17(a)(5)) \$ _____

- ☒ Applicant claims small entity status. See 37 CFR 1.27. Therefore, the fee amount shown above is reduced by one-half, and the resulting fee is: \$ 55.00
- ☐ A check in the amount of the fee is enclosed.
- ☐ Payment by credit card. Form PTO-2038 is attached.
- ☐ The Director has already been authorized to charge fees in this application to a Deposit Account.
- ☒ The Director is hereby authorized to charge any fees which may be required, or credit any overpayment, to Deposit Account Number 13-0480

I have enclosed a duplicate copy of this sheet.

I am the ☐ applicant/inventor.

☐ assignee of record of the entire interest. See 37 CFR 3.71.
Statement under 37 CFR 3.73(b) is enclosed (Form PTO/SB/96).

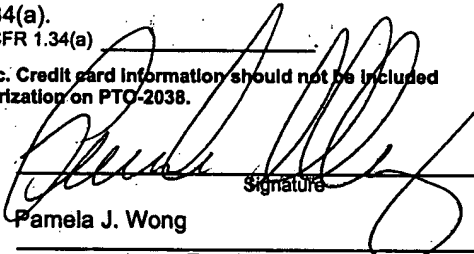
☒ attorney or agent of record. Registration Number 54,765

☐ attorney or agent under 37 CFR 1.34(a).
Registration number if acting under 37 CFR 1.34(a) _____

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

3/31/04
Date

619/235-7792
Telephone Number


Signature
Pamela J. Wong
Typed or printed name

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below.

☒ Total of 1 forms are submitted.

This collection of information is required by 37 CFR 1.136(a). The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 6 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Wong ET AL
App. No.: 09/827,255
Title: COMPOSITIONS AND METHODS FOR THE TARGETED DELIVERY OF
AGENTS TO TREAT LIVER CANCER
Filing Date: April 5, 2001
Art Unit: 1835
Examiner: Bohultz, Douglas

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450
Mail Stop: Fee Amendment

RESPONSE TO AN OFFICE ACTION

Dear Sir:

In response to the Office Action dated December 2, 2003, the time for filing a response being extended to April 2, 2004 by the accompanying Petition and Fee for a One Month Extension of Time, the following amendments and remarks are timely submitted for the Examiner's consideration

Amendments to the Claims are reflected in the listing of claims, which begins on page 2 of this paper.

Remarks begin on page 3 of this paper.

CERTIFICATE OF FACSIMILE TRANSMISSION

I, Pamela J. Wong, hereby certify that this correspondence is facsimile transmitted to the United States Patent and Trademark Office, at 1-703-872-9306, under 37 C.F.R. 1.8, on this 31st day of March, 2004, and addressed to:

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450
Mail Stop: Fee Amendment

Date of transmission: March 31, 2004

Signature:


Pamela J. Wong

AMENDMENTS

In the Claims:

Please amend claims 1, 3-7 and 9, cancel claim 8 and add new claims 11-13.

1. (Currently amended) A composition for the targeted delivery of an active agent to a tissue expressing asialoglycoprotein receptors comprising an effective amount of the agent encapsulated in a liposome having a molar ratio PC:Chol:PS of 11:42:0.025 coupled to desialyated glycoprotein- α 1.
2. (Previously presented) The composition of claim 1, wherein the agent is a drug or a polynucleotide.
3. (Currently amended) The composition of claim 2, wherein the polynucleotide is cDNA encoding a protein, a ribozyme, ~~and or~~ antisense DNA.
4. (Currently amended) The composition of claim 1, wherein the agent is selected from the group consisting of a cytotoxic drugs ~~and~~, a proteins.
5. (Currently amended) The composition of claim 4, wherein the cytotoxic drug is selected from the group consisting of doxorubicin, vincristine, daunorubicin, and amphiphathic amines.
6. (Currently amended) The composition of claim 1, wherein the desialyated glycoprotein- α 1 is coupled to the liposome by an avidin-biotin or thiol-maleamide linkages.
7. (Currently amended) A method for targeted delivery of an active agent to a tissue expressing asialoglycoprotein receptors comprising delivery to the tissue an effective amount of the composition of ~~any of claims 1 to 6~~ or 6.
8. Cancelled
9. (Currently amended) A composition for the targeted delivery of an active agent to a tissue expressing asialoglycoproteing receptors comprising an effective amount of a doxorubicin encapsulated in a liposome having a molar ratio PC:Chol:PS of 11:0.25 coupled to desialytated glycoprotein- α 1 by an avidin-biotin linkage.
10. Withdrawn
11. (New) A method for targeted delivery of an active agent to a tissue expressing asialoglycoprotein receptors comprising delivery to the tissue an effective amount of the composition of claim 1, whereby the agent is a polynucleotide or protein.

12. (New) A method for targeted delivery of an active agent to a tissue expressing asialoglycoprotein receptors comprising delivery to the tissue an effective amount of the composition of claim 11, whereby the polynucleotide is cDNA encoding a protein, a ribozyme, or antisense DNA.

13. (New) A method for targeted delivery of an active agent to a tissue expressing asialoglycoprotein receptors comprising delivery to the tissue an effective amount of the composition of claim 1, whereby the agent is selected from the group consisting of doxorubicin, vincristine, daunorubicin, and amphipathic amines.

REMARKS

Claims 1-7 and 9 were pending in the above-identified application. Claims 3, 5, 6, and 9 were objected to for informalities and claims 1-7 and 9 were rejected under 35 U.S.C. § 112. Claims 1-7 and 9 were rejected under 35 U.S.C. § 103(a). Applicants respectfully traverse these rejections for at least the reasons articulated below.

I. OBJECTIONS

Claim 3

Claim 3 was objected to because the Office Action states that there is no article preceding the term "cDNA" and further states that inserting an "a" just prior to said term would be remedial. Applicants have adopted the Examiner's recommendation and amended claim 3 accordingly. Applicants request that objection on this basis be reconsidered and withdrawn.

Claim 4

Claim 4 was objected to due to the article "a" previous "cytotoxic drugs" is singular, and does not agree with the plural term "drugs" to which it refers, and further states that replacement with "an" would be remedial. Applicants have adopted the Examiner's recommendation and amended claim 4 accordingly. Applicants request that objection on this basis be reconsidered and withdrawn.

Claim 5

Claim 5 was objected to because the term "amphiphatic" is unknown in the art. Applicants have amended claim 5 and corrected the spelling of this term to "amphipathic." Accordingly, Applicants request that objection on this basis be reconsidered and withdrawn.

Claims 6 and 9

Claims 6 and 9 are objected to because the terms "avidinbiotin", "anavadinbiotin linkage", and "asialoglycoproteing" are misspelled. Applicants have amended claims 6 and 9 and corrected the spelling of these terms to "avidin-biotin", "an avidin-biotin linkage", and "asialoglycoprotein" as suggested by the Examiner. Accordingly, Applicants request that objection on this basis be reconsidered and withdrawn.

II. REJECTION UNDER 35 U.S.C. § 112, first paragraph

Claim 3.

Claim 3 stands rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time of the application was filed, had possession of the claimed invention. Specifically, the Office Action also states that the invention of Claim 3 is drawn to the composition of Claim 2, wherein the polynucleotide is cDNA encoding a protein, a ribozyme and antisense DNA. The specification does not describe any such cDNA. Furthermore, while it may be possible to make such a cDNA comprising all three of these elements, neither the prior art nor applicants' specification discloses either prophetically or by way of example any use for the claimed composition. Applicants respectfully traverse for at least the following reasons.

Claim 3 has been amended to recite a polynucleotide "wherein the polynucleotide is cDNA encoding a protein, a ribozyme, or antisense DNA." One example of the written description is found on page 7, lines 9-17. Accordingly, Applicants respectfully request that rejection on this basis be reconsidered and withdrawn.

Claim 7

The Office Action acknowledges that claims 1-6 and 9 are enabled, but maintains that the specification does not reasonably provide enablement for any liposome composition for the targeted delivery of a therapeutic agent to a tissue expressing asialoglycoprotein receptors as claimed in claim 7. Applicants traverse for at least the following reasons.

Claim 7 does not recite delivery of a "therapeutic" agent as stated by the Office Action. As the "targeted delivery of a therapeutic agent" is the basis for the rejection, and claim 7 does not recite a therapeutic agent, Applicants respectfully request that rejection on this basis be reconsidered and withdrawn.

III. REJECTION UNDER 35 U.S.C. § 112, second paragraph

Claims 1-7, and 9 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Specifically, the Office Action states that the claims recite "an effective amount of the agent encapsulated in a liposome" but have not indicated what the amount must be effective for, rendering the metes and bounds of the claim indefinite. One example of the written description for "an effective amount" may be found on page 6, line 26 of the Specification. Applicants respectfully request that rejection on this basis be reconsidered and withdrawn.

The Office Action also states that Claim 4 used Markush-type language referring to "the agent selected from the group consisting of a cytotoxic drugs, a protein" recite neither "and" nor "or," and it is thus unclear whether the two entities are claimed as a conjugate or as separate elements. Claim 4 has been amended and Applicants respectfully request that rejection on this basis be reconsidered and withdrawn.

III. REJECTION UNDER 35 U.S.C. §103(a)

Claims 1-7, and 9 are rejected under 35 U.S.C. §103(a) as being unpatentable over Allen et al, Perez-Solar et al, Prant et al, Martin, Hortobagyi, Menezes et al, Nietchev et al, And Mayer et al, all of record. Applicants traverse for at least the following reasons.

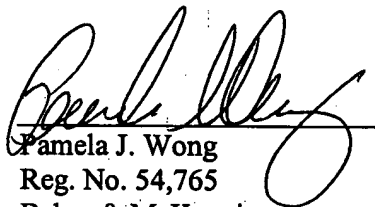
At the outset, the Office Action fails to establish a *prima facie* case of obviousness required under 35 U.S.C. §103. The Examiner has the obligation to identify the suggestion or motivation to modify or combine any of the cited references to show, teach, or suggest all of the limitations of the recited claims. The teaching or suggestion to combine any of these references must be found in the prior art.

Applicants respectfully request that rejection of claims 1-7 and 9 be reconsidered and withdrawn.

CONCLUSION

In view of the foregoing amendments and remarks, Applicants respectfully submit that the pending claims are in condition for allowance, and favorable action is hereby requested. If a telephone interview would be of assistance in advancing prosecution of the subject application, the Examiner is requested to telephone the undersigned at the number provided below. If the Commissioner determines that additional fees are due, please charge our Deposit Account No. 13-0480, Attorney Docket No. 32144183-001336.

Respectfully submitted,



Pamela J. Wong
Reg. No. 54,765
Baker & McKenzie
2300 Trammell Crow Center
2001 Ross Avenue
Dallas, TX 75201
Telephone 619.235.7792
Facsimile 214.978.3099

DECLARATION OF PAMELA J. WONG IN SUPPORT OF

PETITION UNDER 37 C.F.R 1.137(B)

1. My name is Pamela J. Wong and I am over the age of twenty-one (21) years, of sound mind, and fully competent to testify to the following facts. I have personal knowledge that all facts set forth in this Declaration are true and correct.

2. I am registered patent attorney (54,765) at the firm of Baker & McKenzie, which has an address of 2300 Trammell Crow Center, 2001 Ross Ave., Dallas, Texas 75201 and an address of 101 West Broadway, Twelfth Floor, San Diego, CA 92101.

3. I am presently the attorney-in-charge of the file for U.S. Patent Application Serial No. 09/827,255, which has an attorney docket number of 32144183.1336.

4. On March 31, 2004, I executed a Response to Office Action, Petition for Extension of Time-One and facsimile transmission cover sheet and instructed my secretary, Tracey A. Cornish to transmit the filing to the U.S. Patent and Trademark Office.

5. I relied upon the competence of Ms. Cornish to complete my instructions and did not confirm that the facsimile filing had been completed, as it is not my customary practice to review the fax transmission receipt once I instruct my secretary to physically fax the response.

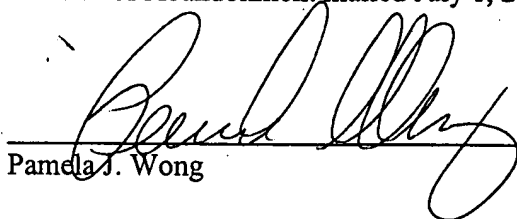
6. Under the belief that the filing had been facsimile transmitted as instructed, I reported the filing of the response to the assignee on March 31, 2004 as evidenced by the attached email correspondence.

7. On June 7, 2004, my secretary, Tracey Cornish, forwarded a phone mail message from Examiner Schultz of the U.S. Patent and Trademark Office inquiring as to whether a response had been filed.

8. Upon reviewing the file, the unintentional error was found and Examiner Schultz was informed of the unintentional failure to respond and our intention to file this petition to revive upon receipt of the Notice of Abandonment.

9, On July 7, 2004, I received the Notice of Abandonment mailed July 1, 2004.

7/21/04
Date


Pamela J. Wong

From: Wong, Pamela J
Sent: Wednesday, March 31, 2004 8:14 PM
To: ADDRESS REDACTED
Cc: Taylor, Jana M; Cheung, Peggy; Mok, Chindy; Cornish, Tracey A.
Subject: HKUST 32144183.1336; TTC.PA.121; USPA 09/827,255; entitled COMPOSITIONS AND METHODS FOR THE TARGETED DELIVERY OF AGENTS TO TREAT LIVER CANCER
Re: U.S. Patent Application No. 09/827,255 entitled "COMPOSITIONS AND METHODS FOR THE TARGETED DELIVERY OF AGENTS TO TREAT LIVER CANCER"; Your file: TTC.PA.121; Our file: 32144183.1336
Dear Rocky and Alice:
Copies of the Response to Office Action and transmittal documents filed today with the U.S. Patent and Trademark Office are attached to this email for your records. If you have any questions, please do not hesitate to contact me.
Best regards,
Pamela

Pamela J. Wong
BAKER & MCKENZIE
101 W. Broadway, Suite 1200
San Diego, CA 92101-3890
Ph: 619-235-7792
Fax: 619-236-0429
email: pamela.j.wong@bakernet.com
<http://www.bakerinfo.com>

DECLARATION OF TRACEY A. CORNISH IN SUPPORT OF

PETITION UNDER 37 C.F.R 1.137(B)

1. My name is Tracey A. Cornish and I am over the age of twenty-one (21) years, of sound mind, and fully competent to testify to the following facts. I have personal knowledge that all facts set forth in this Declaration are true and correct.

2. I am a Legal Secretary at the San Diego office of Baker & McKenzie LLP, which has an address of 101 West Broadway, Twelfth Floor, San Diego, CA 92101.

3. I am responsible for all secretarial duties including transmission of facsimile filings to the U.S. Patent and Trademark Office for patent attorney, Pamela J. Wong of the San Diego office of Baker & McKenzie LLP.

4. On March 31, 2004, Ms. Wong instructed me to file a Response to Office Action and Petition for Extension of Time – one month via facsimile transmission under 37 CFR 1.8 to the U.S. Patent and Trademark Office.

5. I unintentionally failed to facsimile transmit these documents as instructed.

6. On June 7, 2004, I received a phone call from Examiner Schultz of the U.S. Patent and Trademark Office inquiring about the status of the response.

7. On June 7, 2004, I forwarded the phone call message to Pamela J. Wong as evidenced by the attached email correspondence.

7-13-04

Date

Tracey A. Cornish

Tracey A. Cornish

file:///I:/JMT%20ONLY/EMessages/Cornish.txt

From: Cornish, Tracey A.
Sent: Monday, June 07, 2004 3:40 PM
To: Flaim, John G; McCormack, Brian C; Taylor, Jana M; Wong, Pamela J
Subject: Phone call from USPTO Examiner James Schultz on HKUST 1336

Importance: High
James Schultz of the USPTO called to ask about the response to the OA that was due on this application on June 1st.

If it has been filed he wanted to know when it was filed.

His number is 571.272.0763. Please let me know the status of this response and who will be calling Mr. Schultz.

Best Regards,

Tracey A. Cornish
Baker & McKenzie
101. W. Broadway, Twelfth Floor
San Diego, CA 92101 USA
Tel: +1 619 235 7746
email: Tracey.A.Cornish@bakernet.com

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32144183-1336

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Wong ET AL
App. No.: 09/827,255
Title: COMPOSITIONS AND METHODS FOR THE TARGETED DELIVERY OF
AGENTS TO TREAT LIVER CANCER
Filing Date: April 5, 2001
Art Unit: 1635
Examiner: James Schultz

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450
Mail Stop: Fee Amendment

RESPONSE TO AN OFFICE ACTION

Dear Sir:

In response to the Office Action dated December 2, 2003, the following amendments and remarks are submitted for the Examiner's consideration

Amendments to the Claims are reflected in the listing of claims, which begins on page 2 of this paper.

Remarks begin on page 3 of this paper.

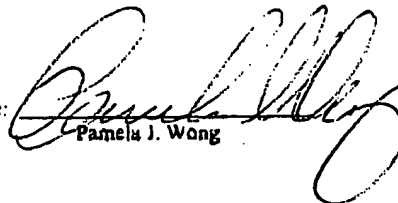
CERTIFICATE OF EXPRESS MAIL No. EV183594695US

I, Pamela J. Wong, hereby certify that the papers enclosed herein are being deposited with the United States Postal Service "Express Mail post Office to Addressee" service under 37 C.F.R. 1.10 on the date indicated below and addressed to:

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450
Mail Stop: Fee Amendment

Date of transmission: July 21, 2004

Signature:



Pamela J. Wong

RESPONSE TO OFFICE ACTION

PAGE 1 of 8

AMENDMENTS

In the Claims:

Please amend claims 1, 3-7 and 9, cancel claim 8 and add new claims 11-13.

1. (Currently amended) A composition for the targeted delivery of an active agent to a tissue expressing asialoglycoprotein receptors comprising an effective amount of the agent encapsulated in a liposome having a molar ratio PC:Chol:PS of 11:42:0.025 coupled to desialyated glycoprotein- α 1.
2. (Previously presented) The composition of claim 1, wherein the agent is a drug or a polynucleotide.
3. (Currently amended) The composition of claim 2, wherein the polynucleotide is cDNA encoding a protein, a ribozyme, ~~and or~~ antisense DNA.
4. (Currently amended) The composition of claim 1, wherein the agent is selected from the group consisting of a cytotoxic drugs ~~and~~, a proteins.
5. (Currently amended) The composition of claim 4, wherein the cytotoxic drug is selected from the group consisting of doxorubicin, vincristine, daunorubicin, and amphiphathic amines.
6. (Currently amended) The composition of claim 1, wherein the desialyated glycoprotein- α 1 is coupled to the liposome by an avidin-biotin or thiol-maleamide linkages.
7. (Currently amended) A method for targeted delivery of an active agent to a tissue expressing asialoglycoprotein receptors comprising delivery to the tissue an effective amount of the composition of ~~any of claims 1 to 6~~ or 6.
8. Cancelled
9. (Currently amended) A composition for the targeted delivery of an active agent to a tissue expressing asialoglycoprotein receptors comprising an effective amount of a doxorubicin encapsulated in a liposome having a molar ratio PC:Chol:PS of 11:0.25 coupled to desialyated glycoprotein- α 1 by an avidin-biotin linkage.
10. Withdrawn
11. (New) A method for targeted delivery of an active agent to a tissue expressing asialoglycoprotein receptors comprising delivery to the tissue an effective amount of the composition of claim 1, whereby the agent is a polynucleotide or protein.

12. (New) A method for targeted delivery of an active agent to a tissue expressing asialoglycoprotein receptors comprising delivery to the tissue an effective amount of the composition of claim 11, whereby the polynucleotide is cDNA encoding a protein, a ribozyme, or antisense DNA.

13. (New) A method for targeted delivery of an active agent to a tissue expressing asialoglycoprotein receptors comprising delivery to the tissue an effective amount of the composition of claim 1, whereby the agent is selected from the group consisting of doxorubicin, vincristine, daunorubicin, and amphipathic amines.

REMARKS

Claims 1-7 and 9 were pending in the above-identified application. Claims 3, 5, 6, and 9 were objected to for informalities and claims 1-7 and 9 were rejected under 35 U.S.C. § 112. Claims 1-7 and 9 were rejected under 35 U.S.C. § 103(a). Applicants respectfully traverse these rejections for at least the reasons articulated below.

I. OBJECTIONS

Claim 3

Claim 3 was objected to because the Office Action states that there is no article preceding the term "cDNA" and further states that inserting an "a" just prior to said term would be remedial. Applicants have adopted the Examiner's recommendation and amended claim 3 accordingly. Applicants request that objection on this basis be reconsidered and withdrawn.

Claim 4

Claim 4 was objected to due to the article "a" previous "cytotoxic drugs" is singular, and does not agree with the plural term "drugs" to which it refers, and further states that replacement with "an" would be remedial. Applicants have adopted the Examiner's recommendation and amended claim 4 accordingly. Applicants request that objection on this basis be reconsidered and withdrawn.

Claim 5

Claim 5 was objected to because the term "amphiphatic" is unknown in the art. Applicants have amended claim 5 and corrected the spelling of this term to "amphipathic." Accordingly, Applicants request that objection on this basis be reconsidered and withdrawn.

Claims 6 and 9

Claims 6 and 9 are objected to because the terms "avidinbiotin", "anavadinbiotin linkage", and "asialoglycoproteing" are misspelled. Applicants have amended claims 6 and 9 and corrected the spelling of these terms to "avidin-biotin", "an avidin-biotin linkage", and "asialoglycoprotein" as suggested by the Examiner. Accordingly, Applicants request that objection on this basis be reconsidered and withdrawn.

II. REJECTION UNDER 35 U.S.C. § 112, first paragraph

Claim 3.

Claim 3 stands rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time of the application was filed, had possession of the claimed invention. Specifically, the Office Action also states that the invention of Claim 3 is drawn to the composition of Claim 2, wherein the polynucleotide is cDNA encoding a protein, a ribozyme and antisense DNA. The specification does not describe any such cDNA. Furthermore, while it may be possible to make such a cDNA comprising all three of these elements, neither the prior art nor applicants' specification discloses either prophetically or by way of example any use for the claimed composition. Applicants respectfully traverse for at least the following reasons.

Claim 3 has been amended to recite a polynucleotide "wherein the polynucleotide is cDNA encoding a protein, a ribozyme, or antisense DNA." One example of the written description is found on page 7, lines 9-17. Accordingly, Applicants respectfully request that rejection on this basis be reconsidered and withdrawn.

Claim 7

The Office Action acknowledges that claims 1-6 and 9 are enabled, but maintains that the specification does not reasonably provide enablement for any liposome composition for the targeted delivery of a therapeutic agent to a tissue expressing asialoglycoprotein receptors as claimed in claim 7. Applicants traverse for at least the following reasons.

Claim 7 does not recite delivery of a "therapeutic" agent as stated by the Office Action. As the "targeted delivery of a therapeutic agent" is the basis for the rejection, and claim 7 does not recite a therapeutic agent, Applicants respectfully request that rejection on this basis be reconsidered and withdrawn.

III. REJECTION UNDER 35 U.S.C. § 112, second paragraph

Claims 1-7, and 9 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Specifically, the Office Action states that the claims recite "an effective amount of the agent encapsulated in a liposome" but have not indicated what the amount must be effective for, rendering the metes and bounds of the claim indefinite. One example of the written description for "an effective amount" may be found on page 6, line 26 of the Specification. Applicants respectfully request that rejection on this basis be reconsidered and withdrawn.

The Office Action also states that Claim 4 used Markush-type language referring to "the agent selected from the group consisting of a cytotoxic drugs, a protein" recite neither "and" nor "or," and it is thus unclear whether the two entities are claimed as a conjugate or as separate elements. Claim 4 has been amended and Applicants respectfully request that rejection on this basis be reconsidered and withdrawn.

III. REJECTION UNDER 35 U.S.C. §103(a)

Claims 1-7, and 9 are rejected under 35 U.S.C. §103(a) as being unpatentable over Allen et al, Perez-Solar et al, Prant et al, Martin, Hortobagyi, Menezes et al, Nietchev et al, And Mayer et al, all of record. Applicants traverse for at least the following reasons.

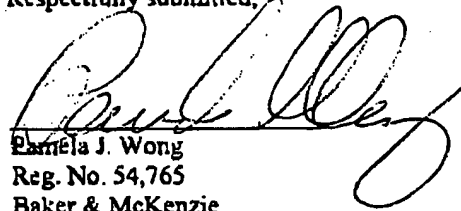
At the outset, the Office Action fails to establish a *prima facie* case of obviousness required under 35 U.S.C. §103. The Examiner has the obligation to identify the suggestion or motivation to modify or combine any of the cited references to show, teach, or suggest all of the limitations of the recited claims. The teaching or suggestion to combine any of these references must be found in the prior art.

Applicants respectfully request that rejection of claims 1-7 and 9 be reconsidered and withdrawn.

CONCLUSION

In view of the foregoing amendments and remarks, Applicants respectfully submit that the pending claims are in condition for allowance, and favorable action is hereby requested. If a telephone interview would be of assistance in advancing prosecution of the subject application, the Examiner is requested to telephone the undersigned at the number provided below. If the Commissioner determines that additional fees are due, please charge our Deposit Account No. 13-0480, Attorney Docket No. 32144183-001336.

Respectfully submitted,



Pamela J. Wong
Reg. No. 54,765
Baker & McKenzie
2300 Trammell Crow Center
2001 Ross Avenue
Dallas, TX 75201
Telephone 619.235-7792
Facsimile 214.978.3099

7/21/04

Date